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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,318	10/15/2001	Marcelo C. Aldaz	UTSC:671US	4492

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT PAPER NUMBER

1642

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/978,318

Applicant(s)

ALDAZ ET AL.

Examiner

Sheela J. Huff

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,8-12,15,18-26,29,32,33,36 and 39 is/are rejected.
- 7) ☒ Claim(s) 74-81 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**Continuation of Disposition of Claims: Claims withdrawn from consideration are 3,4,6,7,13,14,16,17,27,28,30,31,34,35,37,38 and 40-73.**

**DETAILED ACTION**

***Response to Amendment***

The amendment filed on 1/13/05 has been considered. Applicant's arguments are deemed to be persuasive-in-part.

Claims 1-81 are pending.

Claims 1-2, 5, 8-12, 15, 18-26, 29, 32-33, 36, 39 and 74-81 are currently under consideration.

Claims 3-4, 6-7, 13-14, 16-17, 27-28, 30-31, 34-35, 37-38, 40-73 are withdrawn from consideration as being drawn to a non-elected invention.

The rejection of claims 1-2 and 8-9 under 35 U.S.C. 103(a) as being unpatentable over WO 02/12544 (priority to 8/7/00) is withdrawn in view of applicant's amendment.

The objection to the specification is withdrawn in view of applicant's arguments.

The rejection of claims 1, 11, 25 and 32 under 35 U.S.C. 112, first paragraph, is withdrawn (new matter rejection) is withdrawn in view of applicant's arguments.

***Information Disclosure Statement***

The IDS filed 1/13/05 was not signed. However, the cited reference has been made of record by the Examiner in the PTO-892.

***Response to Arguments***

***Claim Rejections - 35 USC § 112***

Claims 1-2, 5, 8-12, 15, 18-26, 29, 32-33, 36, 39 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The reasons for this rejection are of record in the paper mailed 10/8/04.

Applicant argues that the guidelines state that the "written description requirement for a claimed genus may be satisfied through sufficient description of a **representative number of species by actual reduction to practice... or by disclosure of relevant, identifying characteristics**, i.e. structure or other physical and/or chemical properties, by **functional characteristics** coupled with a known or disclosed correlation between function and structure, or by **a combination** of such identifying characteristics" (emphasis added). Applicant argues that the "specific structural and chemical properties" is recited. Applicant states at "at least [20,50,150] contiguous amino acids" meets this limitation. Other than the common structural element between the polynucleotides being a nucleic acid, there is not specific structural or chemical property. Each polynucleotide is composed of a different and distinct sequence of nucleic acids and applicant has not provided a representative number of examples of polynucleotides that encode "at least [20,50,150] contiguous amino acids". In fact, applicant has not provided any examples of such polynucleotides.

Applicant further argues that any undergraduate student could identify the thousands of disclosed species. As stated by applicant, the number of species is enormous and just because any undergraduate student could identify the different species, does not provide sufficient evidence that applicant was actually in possession of those different species.

Applicant argues in the last paragraph on page 16 that the mere recitation of portions of SEQ ID NO. 1 or encoding portions of SEQ ID NO. 2 in the claimed allows a person skilled in the to understand that the inventor was in possession of claimed subject matter. Adequate written description requires more than a mere statement that is part of the invention. The sequence itself is required. Applicant has not provided this for sequences other than SEQ ID NO. 1 and 2.

Thus, from the above, it is clear that applicant has not provided a **disclosure of relevant, identifying characteristics**, such as structure or other physical and/or chemical properties.

With respect to functional characteristics, applicant simply dismisses this as irrelevant. Since no disclosure of structure or other physical and/or chemical properties of the claimed polynucleotides has been made, functional characteristics are not irrelevant. Applicant does states that if functional information were required, the specification does provide this and cites the two putative WW domains. First of all, there is no indication in the claims that the two WW domains are part of the polynucleotides encoding at least 20, 50 150 contiguous amino acids. Second, even if the claims were limited to this, at least 10% of the amino acids can be changed. There

is no guidance in the specification to show a consensus sequences **that is required for function.**

Applicant argues that the claims do not require that anything be on either or both side. By using the terminology "comprises" applicant is claiming such.

### ***Allowable Subject Matter***

Claims 74-81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

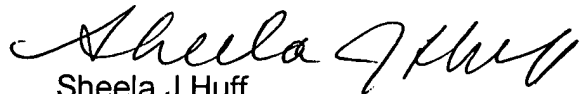
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Mondays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Sheela J Huff  
Primary Examiner  
Art Unit 1642

sjh